DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Tornier
Mrs. Mireille Lemery
Regulatory Affairs Manager
161, rue Lavoisier – Montbonnot
38334 Saint Ismier Cedex
FRANCE

Re: K071948
Trade/Device Name: Aequalis Reversed Adapter
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: July 5, 2007
Received: July 23, 2007

Dear Mrs. Lemery:

This letter corrects our substantially equivalent letter of October 18, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Aequalis Reversed Adapter

Indications For Use:

The Aequalis Reversed Adapter is indicated for use as a component of a total shoulder replacement and is designed to allow the transformation of Aequalis Anatomical (monobloc or press-fit) or Aequalis Fracture stems into components of a reverse shoulder prosthesis without removal during revision surgery. The Aequalis Reversed Adapter is for use only when the implanted humeral stem is well fixed along its entire length and when the patient has a functional deltoid muscle and when the arthropathy is associated with a massive and non repairable rotator cuff-tear.

The Aequalis Reversed Adapter is intended for uncemented use only.

The Aequalis Reversed Adapter is intended to be used with the Aequalis Reversed glenoid which is anchored to the bone with 4 screws and which is for uncemented fixation.

The Aequalis Reversed Adapter is intended to be used with a cemented (Aequalis monobloc or Aequalis Fracture) or uncemented (Aequalis press-fit) stem. The humeral component is not to be revised in the conversion to a reverse shoulder prosthesis and must be well fixed along its entire length.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071948

K071948

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Summary of Safety and Effectiveness information
510(k) Premarket Notification – Aequalis Reversed Adapter

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Device name

Trade name:	**Aequalis Reversed Adapter**
Common name:	Reversed adapter
Classification name:	§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter

Tornier
B.P. 11 - Rue Doyen Gosse
38330 Saint Ismier - France

3) Company contact

Tornier
Mrs Mireille Lémery
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161, rue Lavoisier - Montbonnot
38334 Saint Ismier Cedex - France
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4) Classification

Device class:	Class II
Classification panel:	Orthopedic
Product code:	KWS

5) Equivalent / Predicate device

Anatomical Shoulder™ Inverse/Reverse, Zimmer, Inc, K053274
Aequalis Reversed Prosthesis, Tornier, K061439, K050316, K041873, K030941

6) Device description

The Aequalis Reversed Adapter offers the surgeons the possibility to convert a current implanted standard Aequalis shoulder stem into a component of a reverse prosthesis without removing the well-fixed humeral stem during revision surgery.

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7) Materials

The metal metaphysis of the Reversed Adapter and the U-clip are manufactured from titanium alloy according to ISO 5832-3. The safety screws are manufacturing from Cobalt-Chromium alloy according to ISO 5832-7. The lateralized insert of the Aequalis Reversed Adapter is manufacturing from ultra high molecular weight polyethylene (UHMWPE) according to ISO 5834-2.

8) Indications

The Aequalis Reversed Adapter is indicated for use as a component of a total shoulder replacement and is designed to allow the transformation of Aequalis Anatomical (monobloc or press-fit) or Aequalis Fracture stems into components of a reverse shoulder prosthesis without removal during revision surgery. The Aequalis Reversed Adapter is for use only when the implanted humeral stem is well fixed along its entire length and when the patient has a functional deltoid muscle and when the arthropathy is associated with a massive and non repairable rotator cuff-tear.

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